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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,945	07/22/2003	Edward T.H. Yeh	UTSH:245USC1	2419

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EXAMINER	
MOORE, WILLIAM W	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
06/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,945	YEH ET AL.	
	Examiner	Art Unit	
	WILLIAM W. MOORE	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-51,53-55,57-60,63 and 66-68* is/are pending in the application.

4a) Of the above claim(s) *51,66 and 67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-50,45,53,55,57-60 and 68* is/are rejected.

7)☒ Claim(s) *54 and 63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's Amendment filed 22 February 2008 had been entered, amending claims 45-50, 54, 58, and 68 and canceling claims 53 and 57. Claims 1-44, 52, 61 and 62 have already been canceled, thus claims 45-51, 54, 55, 58-60, 63, and 66-68 remain in the application of which claims 51, 66 and 67 remain withdrawn from consideration as drawn to a non-elected invention. The claim amendments overcome the rejections of record of claims under 35 U.S.C. §§ 102 and 103 over disclosures of Hillman et al., the human cDNA clone IMAGE:684275 in view of Edwards et al., and Adams et al. in view of Edwards et al.

Objection of Record Maintained: Non-Elected Subject Matter

Claims 45-51, 54, and 68 remain withdrawn, in whole or in part, from consideration herein. Applicant's argument at page 4 of the Response filed 22 August 2008 that claims 45 and 54 should be considered "proper linking claims" has been carefully considered but is not persuasive because only the amino acid sequences of the full-length sentrin-specific proteases find an adequate written description in the specification and the divergent subject matters requiring octapeptides of claim 45, which Applicant argues are the basis for a linking claim, instead are new matter, thus cannot properly be considered to the basis for a linking claim. Applicant chose not to elect the subject matter of Group II in the Election made 12 July 2005. Claims 54 and 63 remain conflicting claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-50, 55, 58-60, and 68 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

This is a new ground of rejection because claims 55 and 58-60 had not been included in the rejection of record. Applicant's arguments at pages 7 and 8 of the

Response filed 22 February 2008 have been fully considered but they are not persuasive. Applicant suggests that the formulae of claims 45 and 68 find support in the specification's proposal that any five contiguous amino acids anywhere in SEQ IDs NOs:2, 8 and 10 might define an invention. Yet the specification nowhere indicates any particular pentapeptide or octapeptide, or for that matter any formula, should be considered the core of a sentrin-specific protease. As such the formulae recited in claims 45 and 68 constitute new matter, affecting claims 46-50 and 58-60 depending therefrom. No identification of the recited octapeptides occurs in the specification or in the originally filed claims of the parent application or the instant application and there is no apparent reason why they should have been selected to anchor the sliding arrays of contiguous amino acids described by the dependent claims 46-50, 55, and 58-60, de novo, by Applicant well after the filing dates of the original US priority document and US parent application. There is no basis in the specification to consider the recited selection of four octapeptides to be "relevant identifying characteristics" of a disclosed sentrin-specific protease because nothing in the specification indicates why the rest of the amino acid sequences of SEQ IDs NOs:2, 8, and 10 are any less relevant. Nothing reasonably conveys to one skilled in the relevant art by, e.g., a teaching, a suggestion, or a proposal, that the inventors had considered that the set of octapeptides first formulated in the claims presented on 22 July 2003 might define a polypeptide of the claimed invention at the time the application was filed.

Claims 45-50, 55, 58-60, and 68 remain rejected, essentially for reasons of record, under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for preparing every polypeptide described by the claims,

does not reasonably provide enablement for using any peptide or polypeptide within the genera comprising progressively larger regions of 8 to 200 amino acids selected arbitrarily on the basis solely of including the octapeptide formulae and diverge elsewhere from the disclosed sentrin-specific proteases of SEQ IDs NOs:2, 8, or 10 by amino acid substitutions, deletions and/or insertions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's argument at pages 8 and 9 of the Response filed 22 February 2008 has been fully considered but they are not persuasive. It is agreed that the artisan can make every one of the sliding arrays of contiguous amino acids described by the claims because the specification provides the particular amino acid sequences of the three disclosed sentrin-specific proteases. Applicant again suggests that no undue experimentation would be required of one skilled in the art to use the peptides and polypeptides for making antibodies. But no antibody raised could be determined to

have utility, i.e., the ability to recognize a protease with a disclosed utility – the capacity to specifically recognize and cleave sentrin – unless it recognized, e.g., SEQ ID NO:2. There is no teaching in the specification of the structural elements of the disclosed sentrin-specific proteases and no basis for determining whether or not any small or large array among the myriad species embraced by the rejected claims might fold properly and thereby present authentic antigenic epitopes that would permit one skilled in the art at the time the invention was made to raise antibodies having a specific and substantial utility, i.e., the ability to recognize and bind to the sentrinase of SEQ ID NO:2 that itself has a specific and substantial utility. Where the specification discloses at least one useful embodiment within the scope of claims rejected herein, the polypeptide of claim 63 not subject to this rejection, no rejection is made under 35 U.S.C. § 101 for lack of utility.

Citing early appellate decisions addressing non-analogous art, Applicant expresses the belief that "some experimentation" is admitted by the statutory requirement of enablement. The specification does not provide any guidance, e.g., in the paragraph spanning pages 25-26, and at pages 40-46 therein, that indicates even the extent of experimentation that might be required. Nor do Applicant's arguments establish the extent of experimentation required to enable the use by the artisan or the public of the indistinct genera described by the rejected claims where the specification suggests, at best, that an "empirical approach" might result in random selection of a claimed generic peptide or polypeptide having some use. The proper standard is instead the presence or absence of meaningful guidance, and none can be found in the specification, thus the enablement as to use of the subject matter of the claims rejected herein falls well short of the standard set by the CCPA, the precursor of the Court of Appeals for the Federal Circuit, which is not to "make and screen" any and all possible alterations because a reasonable correlation must exist between the scope asserted in the claimed subject matter and the scope of guidance the specification provides. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 25 (CCPA 1970). As noted in the communication mailed 23 August 2007, the Federal Circuit has approved this standard set by the CCPA in *Genentech, Inc. v. Novo-Nordisk A/S*, 42 USPQ2d 1001 (Fed. Cir. 1997). The rejection of record is therefore maintained.

Conclusion

Claims 54 and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. While no function is now required for the polypeptides of claims 54 and 63, the specification discloses that both have sentrin-specific protease activity.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr Bragdon, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

/Jon Weber, Ph.D./
Supervisory Primary Examiner
Art Unit 1657

/William W. Moore/
William W. Moore
23 May 2007